SWEDISH MEDICAL CENTER

September 28, 2006

Cynthia Watts, Ph.D.
Chair
Certificate of Need Task Force
State of Washington

Dear Dr. Watts:

This letter is the official response of Swedish Health Services to the Washington State Certificate of Need Task Force Report dated September 20, 2006 which was posted online at www.hca.wa.gov/contf. We applaud your foresight in determining the need for a detailed review of our Certificate of Need (CON) process and we congratulate the Task Force for the time and energy expended to address the important issues associated with this review. Our response is divided into five key topic areas:

1. Task Force Process
2. Dependency of the Recommendation on a State Health Plan
3. Broadening the Reach of Certificate of Need
4. Better Enforcement of CON Law
5. The CON Appeal Process

Task Force Process

It is the position of Swedish that the concept of Certificate of Need is a good one; however the means by which the program is administered in Washington State is broken. It is costly, outdated, burdensome and inefficient. Consequently, the signing of House Bill 1688 which mandated the review of the CON Program was welcomed by Swedish. We were nonetheless surprised and concerned by the makeup of the Task Force. Specifically, we regret that no major healthcare provider in the state was represented on the Task Force. In our view this was a serious omission because it is the major providers who use the system most frequently and that have the multi-disciplinary programs, expertise and economics that most significantly impact all of the processes and criteria associated with the CON program. The lack of such representation meant that the Task Force was essentially viewing the state process without some of its most important participants. It is our sincere hope that if the legislature passes any of the CON Task Force recommendations that they will involve the major providers as a practical sieve for the most appropriate adoption and application of the information and recommendations.

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Dependency of the Recommendation on a State Health Plan

In its report, the CON Task Force concluded that "the CON program would be most effective within the context of a broader state health planning process supported by an adequate data reporting system." We understand your support of a comprehensive health planning process and highly approve of your efforts to develop better data systems. However, the state health planning process outlined in the recommendation has a couple of key short comings.

First, the development of a state health plan is a time consuming process that involves the input of many stakeholders and experts. However, it is clear today that we have a broken CON process that is hurting both patients and our healthcare community, and it needs to be fixed *now.* It is important that the changes to the CON program are not delayed until a state health plan is developed as this will only continue the problems that warranted the creation of the Task Force in the first place. Instead, changes to the CON program should be made as soon as possible, with the state health plan development taking place on a separate, but potentially concurrent track.

Second, the task force report is vague on the funding and resource mandates for this recommendation. The creation of a state health planning process would be very costly and resource intensive with questionable benefit to providers. Yet, it appears on page 22 of the report that the total cost of the process would be put on providers through increased CON fees. If the primary purpose of the state health plan is to assist the state, then it should be funded, to a significant degree, through state resources. The funding of improved data systems should also be the responsibility of the state, since the providers will already be bearing the operational costs required to provide and verify the data.

Broadening the Reach of Certificate of Need

We are concerned by the fact that the Task Force was charged with reviewing and attempting to fix a largely ungovernable and broken CON process and has returned with a suggested *broadened* model without improved regulatory mechanics and the critical fiscal and resource mandates. The issue of broadening the reach of Certificate of Need beyond those services reviewed today is of great concern to Swedish in relation to both the resources a broadened reach would consume as well as the unfounded benefits that the proposed expansion would achieve. This fact begs the question as to how a broken system will be improved by expansion.

We agree that all tertiary services "whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume" should undergo CON review. The underlying rationale for this is clear: the link between volume, quality and cost effectiveness have been validated by much research, including that by Leapfrog. However, the other four conditions listed on pages 17 and 18 of the report that would result in a facility, equipment or service undergoing CON review must be questioned. For example, it is proposed that freestanding emergency centers undergo CON review due to "substantial risk for inappropriate utilization," when there is no data to

substantiate this claim. The Swedish run freestanding emergency center in Issaquah has existed since March, 2004 and our data shows that not only has the facility been meeting a large need in the community (over 12,000 visits in its first year alone), its utilization is appropriate and the care delivered is just as (if not more) efficient than that provided in any of our three hospital based emergency departments. Since Swedish was not asked for utilization information by the task force during its deliberations, we can only conclude that the inclusion of freestanding emergency centers on the list of services recommended to undergo CON review is only for competitive reasons; a rationale which is traditionally outside the criterion of national CON processes.

It seems unreasonable that applicants should bear the cost and time associated with CON review for these additional services when they are based on unsubstantiated claims. Until there is clear data to substantiate the claims made on the "proposed services for CON review" they should remain in the "for future study" category.

Better Enforcement of CON Law

The recommendations to improve the monitoring and enforcement of issued CON's and form "stronger connections between CON and licensure of health care facilities and providers," are two of the best recommendations to come out of the task force process. It has been clear to Swedish that once a CON is issued, there is very little follow up or enforcement of the conditions applied. This is especially true when it comes to the provision of charity care, a condition that is applied to almost all granted CON's. It is important to Swedish that all providers who are granted a CON or license to provide a service in our state are held to the same charity care standard, whether they are a non-profit or for-profit entity. In their CON quests, many applicants make charity care claims that do not match the reality of their historical performance or the reality of their expected performance. Given that CON's are often granted on the applicants' word, having increased monitoring and enforcement for CON conditions (and significant consequences for non-compliance) would not only hold applicants accountable, but help to ensure better access to care for the residents of the state.

The CON Appeal Process

We believe that the CON appeal process is a critical issue that needs to be addressed by the Task Force in order to ensure a sustainable and equitable CON program. The task force recommendations speak briefly to "the use of expedited and/or abbreviated review cycles for applications that comply with the state health plan and have minimal impact on area health services." However the recommendations fall short of addressing the whole problem which is partly the review process, but also the realities of the appeal process. The standard *review process* for applications is almost consistently less than a year, but the *appeal process* once a CON is granted can often take several years resulting in a huge economic impact to providers as well as a delay in getting services (occasionally life impacting services) that are documented to be needed in the community to consumers.

One example of how long and appeal process can take is the Swedish application to establish an ambulatory surgery center in Bellevue. The application was filed in November of 2002 and is still under appeal. The result is a significant delay in services to the community. The economic impact is also significant in terms of attorney fees for the parties involved and the loss of critical revenue from the needed service. If the goal of the Certificate of Need program is cost-containment, then the appeal process that is currently in place is in direct contrast to that goal.

In summary, it is Swedish's position that the formation of a task force to evaluate the Certificate of Need process was long over due and that several of the recommendations made by the task force will go a long way toward making the process better. However, it is our opinion that the report in its current state falls short in three critical areas that need to be addressed before the final version of the report is delivered to the legislature:

1. The rational for a state health planning process and its scope need to be better defined and be accompanied by appropriate resource and funding mandates.
2. No additional services should be recommended for CON review until there is clear documentation regarding the claims made to substantiate their review.
3. The inclusion of creative ways to expedite the appeal process for issued CON's.

As one of the largest providers of healthcare services in the state, and one of the most frequent users of the Certificate of Need program, Swedish Health Services would welcome the opportunity to discuss the issues we raise above with members of the CON Task Force. Again, congratulations on your tremendous efforts to date.

Sincerely,

Richard Peterson
President and CEO
Swedish Health Services

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October 4, 2006

via e-mail

Linda M. Glaeser, RN, MS
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Dear Ms. Glaeser,

We would like to commend the Certificate of Need Task Force for its efforts in developing recommendations to improve Washington's Certificate of Need (CoN) Program. The Task Force has spent a great deal of time and energy carefully weighing a number of potential changes to the Washington CoN Program, while giving special attention to the impact that any proposed changes may have on consumers. We have reviewed the September 20 draft report and are pleased with many of the recommendations made by the Task Force thus far.

We emphatically support the Task Force's recommendation that CoN be incorporated into a comprehensive state health plan that will proactively and on an ongoing basis assess health care needs across Washington; a government entity that makes determinations about the proper type and amount of investment to deal with identified health care needs would be a welcome improvement. We are also pleased to see that the Task Force recommends having quality measures such as health outcomes incorporated into the CoN decision making process. Perhaps the most significant recommendations are those that would broaden the scope of projects and services subject to CoN review to include ambulatory surgery centers, cancer treatment centers, diagnostic imaging centers, and purchases of expensive technology. Finally, the collection of additional data, especially data pertaining to outpatient services, is an absolute necessity if we are to fully understand the shifting trends in health care in a manner that allows for informed health care planning.

However, there are two recommendations not incorporated into the September 20 draft report that we believe deserve additional attention – especially if a revamped CoN program is to effectively serve consumer interests. We are primarily concerned that there are not yet adequate provisions to protect

consumers from the rising costs that result from new health care projects and service expansions. Specifically, we encourage the Task Force to consider:

1. Recommending further study of spending thresholds that would automatically trigger CoN review of any facility construction project, service expansion, or equipment purchase with a price tag that exceeds a certain dollar amount; and
2. Recommending the development and implementation of appropriate mechanisms to monitor and limit the capital costs that get passed along to health care consumers in the years following the commencement of a construction project, service expansion, or equipment purchase.

Controlling health care costs to consumers is a primary function of any CoN program. The current Washington statute pertaining to CoN regulation begins by stating that it shall be the public policy of the state that health planning shall promote the health of citizens and provide access to health care while controlling excessive increases in costs (RCW 70.38.015(1)). RCW 70.38.115(2)(b) requires as a criterion of review of CoN applications that the probable impact of a proposal on the cost of and charges for providing health care services in the community be assessed. Current language in the WAC elaborates on the requirement that the cost to consumers of proposed projects and services be assessed as part of CoN review.

Although there is currently language in the state law and regulations requiring an analysis of costs as part of CoN review, ESSHB 1688 suggests that such language has not thus far sufficiently served to guide CoN decision making (see ESSHB 1688 Sec. 1(3)). The bill then encourages the Task Force to consider costs to consumers in its recommendations for CoN reform (see ESSHB 1688 Sec. 3(1)(b), Sec. 3(2)(c)(ii), Sec. 3(2)(d)(ii)(A) and (C)).

The September 20 Task Force draft report indicates that health care costs are in fact one of the major concerns of the Task Force: cost containment is one of the three primary issues that the Task Force sought to address in its work (Draft Report, p. 10); the first point made in the Task Force preamble states that "health care costs are rising at rates substantially above the annual rate of inflation" (Draft Report, p. 10); and the Task Force's revised public policy goal for the CoN program states that the program shall balance considerations of access, existing resources, *expenditure control*, and duplication (Draft Report, p 13, emphasis added). In addition, we recognize that the Task Force recommendation to expand the list of projects, equipment, and services subject to CoN review is intended to aid in controlling rising health care costs. Though we agree with the Task Force that additional projects and services should be subject to CoN review, this appears to be the only substantive recommendation that will help protect consumers from rising health care costs. While it is an important step, we fear that this measure will, by itself, provide only spotty and limited protection to consumers. For the reasons given below, we believe that the two additional recommendations suggested above would help to protect consumers from excessive health care cost increases.

Further Study of Specific CoN Review Thresholds

After considering thresholds as a basis for CoN reviewability, the Task Force has recommended that financial review thresholds not be applied to any facilities, equipment, or services not

specifically identified. The Task Force's rejection of spending thresholds is, we believe, too hasty. Setting spending thresholds that automatically trigger CoN review may well be the single most important tool a CoN program can employ in the effort to contain consumer health care costs.

The current and Task Force recommended practice of reviewing only certain, specifically identified projects means that there will continue to be many large, expensive projects undertaken without any formal consideration of the impact of such projects on consumer costs. In fact, many major hospital projects that do not involve adding new beds or opening a new facility are currently exempt from review and would remain so under the Task Force's proposed revisions. Such capital development projects are not infrequent and have a significant impact on consumer costs.

The costs of all health care expansion and construction projects – not just those costs associated with new beds, select equipment, and certain service expansions – are ultimately passed along to health care consumers. By limiting CoN review to only a fraction of the projects and services that drive health care costs in Washington, the revised CoN program may serve, at best, to contain only a fraction of the health care costs imposed on consumers.

The August 15, 2006, Mercer Report titled "Certificate of Need Assessment – Selected Information on Threshold and Moratorium Criteria" does not make a recommendation on thresholds. However, a close reading of this report's findings seems to support the case for thresholds. One of the most important conclusions of the report is that "opportunities for facilitating State Plan goals can be advanced through the use of thresholds" (p. 2). Since one of the Task Force's primary concerns is the creation and implementation of statewide health care planning, thresholds would appear to be a tool deserving of further consideration. The Mercer Report also finds that thresholds lead to greater opportunities for state oversight and greater opportunities for data collection. The only real drawback to thresholds seems to be that their imposition requires more CoN staff and that, therefore, the use of thresholds increases administrative costs. It is worth determining whether these added administrative costs would, in fact, result in considerably greater savings to consumers in both the short and long terms.

Finally, a review of CoN programs in other states – especially those programs in states such as Vermont and Maine that have proactive and comprehensive CoN programs – finds that these programs incorporate spending thresholds. The "2005 Relative Scope and Review Thresholds" chart compiled by Thomas Piper on behalf of the Task Force indicates that Washington is one of only a handful of CoN states that does not use spending thresholds as a basis for determining whether a planned health care capital project is reviewable. Similarly, 24 of 37 states with CoN programs use a spending threshold to determine whether medical equipment purchases are subject to CoN review.

We strongly encourage the Task Force to recommend further study of spending thresholds. We fear that, by rejecting thresholds, the Task Force may be missing an opportunity to enhance the CoN program's ability to effectively control consumer health care cost increases.

Developing Mechanisms to Limit the Capital Costs that Get Passed on to Consumers

As noted above, the Washington CoN statute already contains clear language about the importance of considering the impact that health care expansion and construction projects have on consumer health care costs. However, the June 2006 Joint Legislative Audit and Review Committee (JLARC) report on the CoN program found that, despite the requirement that cost considerations be a factor in CoN decisions, the CoN program typically has not given much weight to such considerations (p. 12).

It may be that cost considerations have not historically been an important part of CoN review because there is at present no clear guidance in the CoN regulations as to what constitute reasonable or acceptable costs for a capital project. Even worse, there is at present no mechanism to ensure that a capital project – even one with an overall price tag deemed to be reasonable or acceptable – does not result in greatly increased costs imposed on consumers. As it is, a health care facility that receives CoN approval for a project is free to raise consumer prices to whatever level it sees fit in order to recoup project costs over as short a time period as possible.

We encourage the Task Force to recommend keeping the existing statutory language about the importance of controlling consumer health care costs and to recommend developing regulations that would guide the CoN program in effectively enforcing that language. The point is to limit the amount of capital project costs that can be passed on to consumers.

Mechanisms that, if established in the CoN regulations and in the statewide health planning regulations, would help to protect consumers from excessive cost increases include the following:

- A specific limit on the amount of increased revenue per adjusted admission that a health care facility can reap annually with the commencement of a CoN project. Note that Maine currently requests that health care providers limit cost increases to 3% per year. Our suggestion is in the spirit of Maine's "request", but we believe that, to be effective, a specific requirement would need to be incorporated into regulation in a manner that makes the requirement enforceable.
- A requirement that each CoN applicant, as part of the screening and review process for an expansion or construction project or equipment purchase, answer a series of questions about how, exactly, it plans to recoup the costs of the project, over what time period, and what effect the plan will have on the prices it charges to consumers.
- Caps on the total amount of spending on capital projects – whether CoN-reviewable or not – that can be undertaken each year in different regions of the state.

We recognize that the Task Force has deliberated extensively upon a number of possible recommendations and that these deliberations have included some discussion of the issues raised here. Nevertheless, we encourage Task Force members to consider the above recommendations in the month before the Task Force report is finalized and submitted to the legislature. They provide effective and concrete means for ensuring the intent of both ESSHB 1688 and the Task Force: meaningful control over consumer health care cost increases. We believe that these

measures, in combination with those recommended in the September 20 Task Force draft report, will greatly enhance the Washington CoN Program.

Again, thank you for your work toward reforming the CoN program, and thank you for your attention to our concerns and recommendations.

Sincerely,

Will Pittz
Executive Director, Washington Community Action Network

Diane Sosne, RN
President, Service Employees International Union, District 1199NW

WASHINGTON STATE HOSPICE & PALLIATIVE CARE ORGANIZATION

MEMO

To Carolyn "Cindy" Watts, PhD, Chair, Certificate of Need Task Force
Representative Eileen Cody, RN, Task Force Member
Linda Glaeser, Lead Task Force Staff

From: Anne Koepsell, MHA, RN, Executive Director, Washington State Hospice & Palliative Care Organization

Anne E Koepsell, MHA, BSN, RN

Date: October 6, 2006

Re: CN comments (in conjunction with HCAW and Family Home Care)

Thank you for the opportunity to submit this Memo as a replacement for Memos sent on May 23rd and June 6th. At the time those Memos were written we did not completely understand Representative Cody's question concerning the home health and hospice marketplace as it relates to certificate of need (CN). While we understood that Representative Cody was asking if CN should apply to all portions of the marketplace, we did not understand that she envisioned two separate CN routes: one for agencies that wanted to access Medicare reimbursement, primarily, and one for agencies that wanted no access to Medicare reimbursement.

Summary: In response to Representative Cody's question, as we now understand it, we do not recommend requiring CN for home health or hospice agencies that do not want access to the Medicare marketplace. The following contains our rationale, as well as background information.

- Medicare is the key reimbursement source for home health services. In a survey of our members, respondents indicated that 76% of their revenue came from Medicare; 17% from Medicaid; 6% private insurance; and 1% private pay.
- The Medicare benefit for home health care has rigorous coverage criteria that must be met in order for a beneficiary to receive care. The Medicare benefit is restrictive and does not cover long-term chronic care needs, such as custodial or maintenance care. Non-Medicare services fill that gap.
- Of the 93 state licensed home health agencies, 61 are Medicare certified. Of the remaining 32 state licensed only agencies, 8 are affiliated with Medicare certified agencies.
- The non-Medicare home health marketplace has certain constraints that make it very unlikely that it would produce demand for these services, unrelated to need.

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    - The only way a non-Medicare certified agency can receive reimbursement for traditional Medicare services is if there is no Medicare-certified agency that can provide them in a given service area. This happens infrequently.
    - Non-Medicare certified agencies have far less access to third party reimbursement than Medicare certified agencies. In a survey of our membership, over 75% said that third party payers required Medicare certification or JCAHO accreditation.
    - Non-Medicare-certified agencies rely heavily on private pay, or persons paying without regard to any insurance. This portion of the market is particularly susceptible to traditional economic principles of supply and demand because consumers are paying out of pocket.
    - Some non-Medicare certified home health agencies provide services through contracts with DSHS' Aging and Adult Services Division. But, we believe this number is relatively low because the reimbursements are below cost.
- Non-Medicare home health services are based on a different delivery model than Medicare home health services. Medicare home health is a " per visit" and "intermittent" or "part-time" service which means that skilled health care professionals (nurses, PT's, OT's, home health aides, etc) provide a service during an appointment period that could last from 15 minutes to over an hour. As noted above, Medicare services are not all inclusive and do not cover custodial or health maintenance services.
- Non-Medicare home health services are "hourly" meaning that health care professionals are in the home providing care on a more continuous or "hourly" basis, as determined by the consumer's needs and their ability to pay.
- The majority of Medicare agencies are not interested in providing "hourly" care. As noted above, it is a completely different model of care. And for those that are interested, they often obtain a separate home health license.
- Medicare agencies rely on the existence of non-Medicare agencies to fill in the gap for people by providing these additional services that often make the difference in a person being able to remain in their own home.
- State licensed only, or non-Medicare certified home health agencies, are not a competitive threat to Medicare certified home health agencies because their "business" is so completely different.
- For hospice agencies, there is essentially only one marketplace. Virtually all state licensed hospice agencies are also Medicare certified. For hospice, services are either covered under Medicare or private insurance, or it ends up as charity care. Hospice is a comprehensive service.

The following comments provide some additional detail.

1. The Department of Health (DOH) licenses in-home services agencies according to the following categories when specific regulatory requirements are met under Chapter 70.127 RCW: home health, hospice, home, care, and hospice care centers. Because there is the most confusion

between home health and home care agencies, we are providing some additional detail.

2. Home health agencies are required to be licensed by the Department of Health (DOH) under Chapter 70.127 RCW. Home health agencies are defined as "a person administering or providing *two or more* home health services…to individuals in places of temporary or permanent residence." Home health services include nursing, home health aide, physical, occupational, speech and respiratory therapies, nutritional services, medical social services and home medical supplies or equipment. Persons that provide a *single* service may *elect* to become licensed, but are not required to be licensed.
3. Home health agencies that want to access Medicare reimbursement must be state licensed, Medicare certified, and have a certificate of need for their service area. A service area is at least one county, but can be more than one county. The Department of Health is the surveyor for Medicare certification.
4. Home care agencies are required to be licensed by the Department of Health. Home care agencies provide *nonmedical* services and assistance to include personal care such as assistance with dressing, feeding, and personal hygiene to facilitate self-care; homemaker assistance with household tasks, such as housekeeping, shopping, meal planning and preparation, and transportation; respite care assistance and support provided to the family; or other nonmedical services or delegated tasks of nursing.
5. Home care agencies have *never* been subject to certificate of need. We are not recommending that this be changed. The primary source of reimbursement for home care agencies is through DSHS' Aging and Disability Services Administration (ADSA). While the number of applicants for home care agency licensure has been increasing, a significant number of these applicants, once granted licensure, have no or very few clients. That's because in order to access ADSA programs and their clients, AAA's require agencies to have a certain number of years experience in providing services. This requirement essentially limits the number of the newer providers that deliver services, unless they can find a niche in the private pay marketplace.

Based on this information and analysis, we do not recommend any change to the scope of the certificate of program for home health, hospice, or home care agencies. We do not recommend requiring certificate of need for home health or hospice agencies that do not want access to the Medicare marketplace. We do believe certificate of need should be retained for those home health and hospice agencies that want access to Medicare. Please see our April 2006 Memo to Chair Watts for more details.

Cc: Donna Goodwin, Family Home Care
Donna Cameron, HCAW
Gail McGaffick, JD

Washington
State
Hospital
Association

June 27, 2006

Cindy Watts, Ph.D.
Chair, Certificate of Need Task Force
Professor, University of Washington
P.O. Box 357660
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Madam Chair:

As we near the final stages of the 2005-06 Certificate of Need Task Force, it is time to express some of WSHA's specific hopes and concerns. The project has been a learning experience for everyone. The work of the task force and the technical group is very significant and likely a center feature of the 2007 legislative session.

I agree with Jon Smiley's comments sent to you last week. Here are some additional thoughts.

- Having the Department of Health (DOH) license free-standing ambulatory surgery centers and gather data from them would be a major step in improving Certificate of Need (CON).

- Regarding rural hospitals, I believe there are other factors to consider beyond Jon's points:

    - Having modern equipment is essential to overcoming the challenges in recruiting physicians to rural areas.
    - Critical Access Hospitals are required to be part of the state's trauma system, which suggests a reasonable level of sophisticated technology.
    - And, as noted in the new Institute of Medicine report, *Hospital-Based Emergency Care: At the Breaking Point*, rural hospitals and their emergency departments are absolutely necessary for large-scale disasters and surge capacity.

- WSHA agrees with the recommendations of the Joint Legislative Audit and Review Committee (JLARC) report. But the report may fall short of the hopes of those who worked on HB 1688 and argued for a thorough analysis of DOH's performance conducting CON. The following are places WSHA and the members of the CON Technical Advisory Committee (TAC) with the most experience regarding the state's Certificate of Need program believe JLARC's report lacks some depth:

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- A key factor in the high number of CON appeals since 2004 is that the State Health Plan is out-of-date. The nearly 20-year old plan no longer provides clear guiding policies for the Department of Health – which means DOH staff cannot deliver consistent analysis and, we believe, consistent decisions. The lack of consistency is one reason for so many appeals.
- The sharp rise in the number of CON decisions appealed in 2003 and 2004 was, in part, due to the department's unilateral changes in the method for determining the need for kidney dialysis.
- JLARC staff did not comment on the nature of the 33 appeals still pending, reducing the understanding of the causes.
- Another factor JLARC could have addressed directly but did not is the year-by-year composition and adequacy of the staff conducting CON since 2000. WSHA and other parties agreed to increased fees in 2003, I believe, with the understanding the department would increase staffing and reduce delays. We appreciate that these are difficult positions to fill and train, but it is disappointing that two positions remained vacant until this study began.
- Further, JLARC staff could have looked at DOH's performance in making determinations of eligibility for CON review.

Cindy, your management of the task force is admirable. I appreciate the greater opportunity to ask questions or offer explanations during the meeting. Please call me at 206.216.2514 if you have questions about this letter.

Sincerely,

Robb Menaul

Robb Menaul, FACHE
Senior Vice President

cc: Senator P. Thibaudeau
Senator A. Deccio
Representative E. Cody
Representative B. Bailey
Steve Hill

Washington
State
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October 3, 2006

REVISED

Cindy Watts, Ph.D.
Chair, Certificate of Need Task Force
Professor, University of Washington
P.O. Box 357660
Seattle, WA 98195

Dear Cindy:

As the CON Task Force winds down, I want to thank you and the members of the task force members for your patience, stamina, and wisdom in completing this assignment.

This letter conveys the state hospital association's analysis of the nearly finished CON Task Force Report. The comments are grouped into substantive or editorial comments. In general, they are ordered by topic and page number in the report.

Overall Expectations for Certificate of Need

- Frequently during Task Force and Technical Advisory Committee discussions, members of the two groups reminded each other not to elevate expectations for Certificate of Need (CON). The state can only regulate a small portion of the health care economy. Improving the CON program cannot stop health care inflation, cannot reform the health care system, and cannot implement our state's public health plans, for example the disaster readiness and Public Health Improvement plans.
- That does not mean that CON is without value. Far from it. CON has a definite role in protecting access to necessary care and those providers, especially community hospitals, which have a community service mission, obligation, or commitment. CON can help prevent entry into the market place by competitors who select the healthiest, best insured patients and leave the sicker, poorly insured patients to the community hospital, thereby diminishing the community hospital's ability to provide needed, low-margin services, for example, obstetrics.

Criteria for Review

- On page 14 the report outlines the rationale for the recommendation to link CON and licensure of health facilities. WSHA supports the recommendation.

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- On page 15, WSHA agrees with the language in para. (2) (c) which puts the recommendation from page 14 (bullet point above) into CON review language.
- On page 15 near the bottom, para. (2) (l) is not clear. I think the intent would be clear if it read, "For other CON regulated services, the applicant must provide charity care equal to the average of competitor providers in the service area."

Proposed for Continued (CON) Review

- On page 19 under the headline Surgery, three new items show up (also on Appendix B-2 lists). They are: General inpatient, Hospital outpatient, and Hospital-based ambulatory surgery centers. This is probably an attempt to clarify, but it only confuses. These three items were not in earlier drafts and they could be misinterpreted. They should be deleted. Hospitals are reviewed when they want to add beds, convert beds to other categories – e.g. – from acute to long-term care, have a change in ownership, or seek to add a tertiary service or build a new hospital. The present rules are clear.

Proposed for New Review

- On page 20 several new types of equipment and services are listed to come under CON review as a result of the Task Force's August 16 meeting. Up to that point the Task Force and the Technical Advisory Group were comfortable with an earlier conclusion that they did not have the technical expertise to add items to the list of reviewable services. WSHA prefers that the legislature authorize expert review panels convened by the Department of Health. The panels would evaluate the addition of new technologies/services for CON review against a legislatively-approved set of criteria and make recommendations to the department.

Mechanisms to Monitor

- Sources of Revenue - On page 22, para. (1) talks about sources of revenue. WSHA believes this statement should be stronger and more specific. If the legislature agrees with the changes proposed in the report, for example, that a new and regularly updated state health plan should happen, the budget for state planning related activities will increase significantly. Application fees alone will not support that additional overhead, nor should they. Because a sound state health plan will benefit the entire state, general fund money should be directed to the Department of Health to accomplish improvements.

- Penalties for non-compliance – On page 22, the examples of penalties include fines. WSHA is opposed to monetary fines as a motivator. Withdrawal of a license, or the threat thereof, is a much stronger motivator. The legislature affirmed this position just a few years ago. WSHA recommends the last sentence be re-worded.

Program Processes

- At the top of page 24, there is a recommendation to continue the current process flow for CON. WSHA members disagree. The results of CON would be challenged less frequently if the ex parte curtain for no further exchanges between the applicant and DOH dropped later in the process. Some other states, for example, Oregon, allow the state to release a proposed decision or preliminary finding before cutting off communications. This allows the applicants and interested parties to correct misinterpretations or explain things earlier and avoid being frustrated by and then appealing a negative decision based on bad or misunderstood information.

- Staffing – On page 24, para. (7) speaks to the need for resources, including staff. The department needs a full complement of professionally trained staff to conduct CON. Developing and using various demand formulae to implement CON for services as diverse kidney dialysis, home health, and neonatal intensive care as well as jousting with physicians, consultants, hospital executives, and attorneys requires the best staff available.

Editorial Comments

- Purpose and Goals – On page 12, para. (1) is not clear. It would be clearer to place a period after "state" on the second line and start a new sentence that would read, in part, "Such a process should be undertaken biennially…"
- Statutory Modification – On page 22, para. (1) would be clearer if the action phrase "be established" was placed early in the sentence, not at the end.

This project was very helpful in obtaining more information to guide the legislature in considering changes to the Certificate of Need program. Thank you for your leadership.

Sincerely,

Leo Greenawalt
President

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WashingtonStateMedicalAssociation

October 6, 2006

MEMO TO: Members, Certificate of Need Task Force

FROM: W. Hugh Maloney, MD, President - Elect

SUBJECT: POSSIBLE EXPANSION OF CERTIFICATE OF NEED

First, let me thank the Task Force for allowing the Washington State Medical Association (WSMA) to share our views on the discussion that will occur on August 16th regarding the possibility of expanding the Certificate of Need (CON) Program. We understand that the task force has expended considerable effort on this issue over the past couple of years, and while the effort is most laudable, the possible results are exceedingly problematic.

The possibility of expanding the CON program to outpatient services such as clinic owned ambulatory surgery centers, diagnostic imaging services and equipment, and physician office-based services is stunningly at odds with the broad societal consensus that market forces should be allowed to drive the provision of health care services in the direction of higher quality and lower costs. Indeed, that has been part of the Governor's health care agenda. The principle argument for expansion of the CON program is that a command and control structure will reduce health care expenditures by controlling the supply of services made available to patients in Washington State. CON, in its current form, has not been shown to control costs. Why would expansion of an ineffectual anachronism do so?

On behalf of the 9,000 members of the WSMA, we ask that the Task Force not recommend expansion of the CON program. As stated, the CON program is a regulatory apparatus that does not, and has not, achieved its primary goal of controlling health care expenditures. The CON program as it is presently executed by statute places barriers to introduction of important services and does nothing to improve cost outcomes. CON decisions grant franchises to the receiving entities, and block other viable and cost effective models from entering the marketplace. Most of the CON program should be repealed. It makes no sense to expand it.

The attached document[1] reviews the existing literature on the lack of success of CON programs throughout the United States. When you review this document, it is hard to conclude that the prudent approach to controlling health care expenditures is to expand the program into outpatient services. As a matter of fact, the Joint Legislative Audit and

[1] Produced by the American Medical Association (AMA) in July 2006

Review Committee of the Washington State Legislature adopted a report in 1999 that questions the success of the CON program on controlling health care expenditures. The report, conducted by the Health Policy Analysis Program of the University of Washington, states the following:

> *"The study found **strong evidence** (emphasis added) that CON is not an effective mechanism for controlling overall health care spending."*

A much wiser strategy for controlling health care expenditures is to implement provisions that refine purchasing strategies used by the state. The Legislature has already granted this ability to the state's agencies to develop standards to be used in reimbursement decisions.

These directions to the agencies are as follows:

- 2005-2007 Biennial Budget: "The Departments of Social and Health Services, Labor and Industries and the Health Care Authority, in collaboration with affected health care providers, facilities, and contracted health plans, shall design and implement a joint health purchasing project that links payment to health care provider or facility performance, particularly where such performance is expected to improve patient outcomes or where there are wide variations in clinical practice used to treat a condition or illness. The purchasing effort shall **utilize evidence-based performance measures** (emphasis added) that are designed to improve quality of care and yield measurable and significant savings. The project shall include payment mechanisms that create incentives to improve quality of care. On or before December 1, 2006, the agencies shall report to relevant policy and fiscal committees of the Legislature on the status of the purchasing project, including actual and anticipated savings."

- HB 1512 (Chapter 446, Laws of 2005): "The Administrator shall, in collaboration with other state agencies that administer state purchased health care programs, private health care purchasers, health care facilities, providers, and carriers, **use evidence-based medicine principles** (emphasis added) to develop common performance measures and implement financial incentives in contracts with insuring entities, health care facilities, and providers that:

  a). Reward improvements in health outcomes for individuals with chronic diseases, increased utilization of appropriate preventive health services, and reductions in medical errors; and,

  b). Increase, through appropriate incentives to insuring entities, health care facilities, and providers, the adoption and use of information technology that contributes to improved health outcomes, better coordination of care, and decreased medical errors."

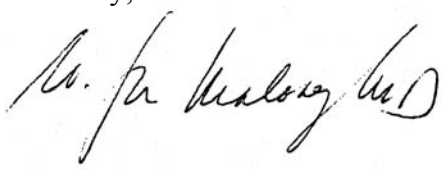
- HB 2575 (Chapter 307, Laws of 2006): This measure provides for the establishment of a Health Technology Assessment Program. Through the program health technologies will be evaluated and decisions will be made on whether or not to cover certain technologies in programs administered by the State of Washington. Health Technology

is defined as: "medical or surgical devices and procedures, medical equipment, and diagnostic tests."

We strongly urge you to not further complicate the health care marketplace by expanding the CON program into outpatient services.

Our Olympia staff remains available to any member of the Task Force to discuss this important issue. Please contact Len Eddinger at (360) 791-6088.

Sincerely,



W. Hugh Maloney, MD
President-Elect

cc: WSMA Executive Committee
Thomas J. Curry, Executive Director/CEO
Len Eddinger, Senior Director, Legislative and Regulatory Affairs

Attachment

CON Task Force Memo

AMA
AMERICAN
MEDICAL
ASSOCIATION

THE EXPERTS HAVE SPOKEN: CERTIFICATE OF NEED PROGRAMS DO NOT CONTROL HEALTH CARE COSTS AND ARE NOT AN EFFICIENT WAY TO IMPROVE QUALITY

- **"At a minimum, it seems fair to conclude that direct CON effects on costs are not negative"** *(meaning that CON did not directly reduce costs).*

Source: D.S. Salkever, "Regulation of Prices and Investment in Hospitals in the United States," Handbook of Health Economics, Volume 1B, Eds. Culyer and Newhouse, Elsevier Science, 2000 p. 1527. *(Chapter 28 of the Handbook by Salkever contains an extensive review of the academic literature analyzing the effectiveness of CON).*

- **"With its roots on the rapidly disappearing cost-based, third party reimbursement mechanisms of the past, CON is becoming clearly less relevant as a cost containment mechanism."**

Source: Michigan Department of Community Health, "The Michigan Certificate of Need Program," February 2005, page 12. *(This study is one of the most recent and comprehensive state analyses of CON's impact on health care costs and quality).*

- **"Numerous studies have shown that CON has not controlled overall hospital spending. One study found that CON actually increased hospital expenditures."**[1] (Page 10).

- **"The weight of the research evidence shows that CON has not restrained overall per capita health care spending."**[2] Id.

- **"In some instances, CON rules are used to restrict access by preventing the development of new facilities."** (Page 6).

- **"Washington's CON law has had no effect on improving access."** Id.

- **"Evidence about the effect of CON on quality is inconclusive. The evidence is weak regarding the ability of CON to improve quality by concentrating volume of specialized services. CON does not provide an ongoing mechanism to monitor quality."** (Page iii).

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[1] Based on Conover, Christopher, and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy, and Law*, Vol. 23, No. 3, June 1998; Mendelson, Daniel M., and Judith Arnold, "Certificate of Need Revisited," *Spectrum*, Winter 1993; Delaware Health Care Commission, "Evaluation of Certificate of Need and Other Health Planning Mechanisms," Volume I, Final Report, May 1996; Custer, William S., Ph.D., "Certificate of Need Regulation and the Health Care Delivery System," Center for Risk Management and Insurance Research, Georgia State University, February 1997.

[2] Id.

- **"...CON is not an effective mechanism for controlling overall health care spending...In addition, CON has not been very effective in controlling hospital costs."** Id.

Source: Washington State Joint Legislative Audit and Review Committee, "Effects of Certificate of Need and Its Possible Repeal," January 1999.

- **An analysis of CON programs from 1966 to 1982 found that CON appears to increase per capita hospital expenditures: per capita hospital expenditures were 20.6 percent higher in states with CON when compared with those without CON.**

- **CON may have increased costs because it protected incumbent organizations from the competition of new entrants into the market.**

Source: Lanning, J. A., Morrisey, M. A., Oshfedlt, R. L. "Endogenous Hospital Regulation and its Effects on Hospital and Non-Hospital Expenditures." *Journal of Regulatory Economics*, 1991, 3 137-154.

- **Greater competition (as opposed to regulation of entry) has been found to lower average expenditures per patient and mortality among Medicare patients being treated for heart attacks in the 1990's.**

Source: Kessler, D. P., McClellan, M. B. "Is Hospital Competition Socially Wasteful?" *The Quarterly Journal of Economics*, 2000, 115 (2), 577-615.

- **"CON laws have been found to deter entry and allowed hospitals to raise prices 4.0 to 4.9 percent. And the longer CON had been in effect, the higher hospital costs and services."**

Source: Noether, M. "Competition among Hospitals." *Journal of Health Economics*, 1988, 7 259-284.

- **"There is no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations."**

- **"It is doubtful that CON regulations have had much effect on quality of care, positive or negative."**

Source: Conover, C.J., Sloan, F.A., "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?" *Journal of Health Politics, Policy and Law*, 1998, 23(3), 455-481. *(This study examined health care spending from the late 70's to 1993, specifically looking at spending prior to, then after, states repealed their CON laws).*

- **"In searching the scholarly journals, one cannot find a single article that asserts that CON laws succeed in lowering healthcare costs."**

- **CON "has elicited a remarkable evaluative consensus -- that it does not work."**

Source: Patrick John McGinley, "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System." 23 Fla. St. U. L. Rev. 141, 157 Summer 1995.

- **"CON is not an effective mechanism for controlling *overall* per capital health care spending. While CON laws can be effective in slowing the expansion of some services, many other factors affect health care costs (e.g., labor, physicians services) that CON laws have not attempted to control."**

- **"CON has not been very effective in controlling *hospital* costs. Not all hospital services are covered by CON, and the program is not always effective in controlling supply."**

- **"CON has limited ability to impact the overall cost of health care or to address issues raised by care for the uninsured and underinsured."**

- **"It may make little sense to rely on CON to carry out quality assurance functions that might be better approached by more direct and cost effective means such as regulation and licensing and/or outcome reporting to the public."**

- **"[R]esearch findings are inconclusive regarding the ability of CON to improve quality by concentrating volume of specialized services at certain facilities. Evidence is mixed regarding CON's effect on the market share of for-profit providers and any resulting impacts on quality."**

Source: Conover, C.J., Sloan, F.A., "Evaluation of Certificate of Need in Michigan," Center for Health Policy, Law, and Management, Terry Sanford Institute of Public Policy at Duke University, study commissioned by the Michigan Department of Health, May 2003, p. 132.

- **"State legislators have little to fear in the way of cost consequences from the repeal of CON laws...CON laws are not an effective means of limiting Medicaid expenditures..."**

Source: Grabowski, D. C, Ohsfeldt, R. L., Morrisey, M. A. "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Expenditures." *Inquiry*, 2003, 40 (2), 146-157.

- **"Strong evidence was found that neither voluntary rate setting nor CON review exerted any constraining effect on costs per capita, utilization, and capital investment."**

Source: Ashby, J.L., "The Impact of Hospital Regulatory Programs on Per Capita Costs, Utilization, and Capital Investment." *Inquiry*, 1984 Spring, 21(1):45-59.

- **"The available evidence indicates that certificate-of-need programs have [not] exerted an appreciable influence on costs."**

Source: Schwartz, W.B., "The Regulatory Strategy for Controlling Health Costs." *New England Journal of Medicine*, 1981 Nov. 19,305(21):1249-55.

APPENDIX

Critique of 2002 Daimler Chrysler, Ford, and General Motor CON Studies

In 2002 Daimler Chrysler, Ford Motor Company, and General Motors released studies purporting to support the claim that CON programs could help control health care costs.

These studies have been subjected to several criticisms:

1. The studies failed to account for cost differences in the CON v. non-CON states that were completely independent of CON (See Bruce Darwin Spector, "A Review of Certificate of Need Health Care Policy Programs: At the Intersection of Science and Politics, paper prepared specifically for the Washington State Health Care Authority, December 2005, p. 45.

2. The studies appear to not take into account local factors which could influence health care costs, e.g., whether a factory "was in a large city with a high cost health care system not attributable to CON or lack of CON." Id.

3. The studies examined only eight states (Michigan, Indiana, Kentucky, New York, Missouri, Wisconsin, Ohio, and Delaware) with and without CON, and states with CON enforced their programs with varying degrees. John Barnes, "Failure of Governmental Central Planning: Washington's Medical Certificate of Need Program," Washington Policy Center, January 2006, p. 8.

4. The studies failed to establish the connection between CON laws and the cost of health care benefits. *"Built into the report is the assumption that because the cost of health care for a certain segment of the population (auto company employees) in a few states is less than in a few other states, Certificate of Need laws that are merely intended to reduce health care costs actually do work. One condition is not necessarily related to the other, and unless a cause-and-effect relationship can be established, the statistics are meaningless in the discussion of Certificate of Need's effectiveness."* Id.

Also, Professors Conover and Sloan, who produced an evaluation of Michigan's certificate of need program for the Michigan Department of Community Health, and which the Department incorporated into its February 2005 comprehensive study of Michigan's CON program, stated that ***"upon reviewing a large body of national and Michigan-specific material regarding acute care CON, including an analysis of what happened in states that dropped acute care CON...There is little evidence that CON results in a reduction in costs and some evidence to suggest the opposite."*** See Michigan Department of Community Health, "The Michigan Certificate of Need Program," February 2005, page 34.